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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO. <sup>1</sup>	CONFIRMATION NO.
09/828,870	04/10/2001	Thomas D. Chittenden	104322.147 US5	7819
24395	7590	05/17/2005	EXAMINER	
WILMER CUTLER PICKERING HALE AND DORR LLP THE WILLARD OFFICE BUILDING 1455 PENNSYLVANIA AVE, NW WASHINGTON, DC 20004			SCHULTZ, JAMES	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/828,870	CHITTENDEN ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	J. D. Schultz, Ph.D.	1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 01 March 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 40-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 40-55 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 7/11/01.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election with traverse of Group II, drawn to methods of identifying an agent capable of modulating GD domain mediated heterodimerization between SEQ ID NO: 36 and Bcl-x<sub>L</sub> in the reply filed on November 18, 2004 is acknowledged. Applicants have clarified the extent to which each of SEQ ID NOS: 35-41 will hybridize with each other, which was apparently and inadvertently unclear in the claims submitted in the amendment filed June 1, 2004. The election of Group II, and also of SEQ ID NO:36 and Bcl-x<sub>L</sub> is considered fully responsive, and the amendment submitted November 18, 2004 has been fully entered and examined herein below.

The traversal is on the ground(s) that it would not be a burden to search the inventions of the two Groups together because it is asserted that the search for methods of identifying agents that modulate GD domain heterodimerization would result in the ability to assess patentability of methods drawn to GD domain homodimerization, and because they are classified in the same class. Furthermore, applicants argue that it would not be a burden to search the nucleotide sequences of SEQ ID NOS: 35-41. However, these arguments are considered moot in view of applicants' cancellation of the non-elected subject matter.

The requirement is still deemed proper and is therefore made FINAL.

***Claim Objections***

Claim 52 is objected to because of the following informalities:  
heterodimerization appears to be misspelled as “herodimerazation”. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.  
  
Claim 53 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 53 is drawn to a method of using a sequence comprising a GD domain as characterized in SEQ ID NO: 36. One of skill in the art would not know how to construe the term “characterized”. It is not clear if the term characterized represents open or closed transitional language, or even if said language encompasses substitutions or variants thereof. Accordingly, one of skill in the art could not be apprised as to the metes and bounds of the claim. For the remainder of this action, such language is interpreted as open language, akin to “comprising”.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 46-51, and 53-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Chittenden et al. (U. S. Patent Number 5,656,725).

As a first note, priority is claimed through U.S. Application Numbers 09/236,385, 08/908,795, and 08/440,391. However, SEQ ID NO: 36 first appears only in 09/236,385. Although SEQ ID NO: 2 of 08/908,597 is a 28mer amino acid sequence which contains embedded within it SEQ ID NO: 36 (a 20mer), priority is denied to this application, because one of skill would not have been led from SEQ ID NO: 2 of the parents to the instant SEQ ID NO: 36, because there is no teaching within the specification that SEQ ID NO: SEQ ID NO: 36 is a preferred or contemplated embodiment of SEQ ID NO: 2. Accordingly, priority of the instant claims is accorded to the filing date of U.S. Application Number 09/236,385, which is January 25, 1999.

The invention of the above claims is drawn to a method of screening for modulators of the interaction of a sequence comprising SEQ ID NO: 36 and Bcl-XI, wherein Bcl-XI may be labeled, or may be a fusion protein which may be GST-Bcl-XI, or wherein said agent augments or inhibits dimerization between a sequence comprising SEQ ID NO: 36 and Bcl-XI. The claims are also drawn to a method of screening for modulators of apoptosis comprising screening for modulators (enhancers or inhibitors) of the interaction of a GD domain as characterized in SEQ ID NO: 36 (see above under 35 U.S.C. § 112 second paragraph for explanation of “characterized”).

U. S. Patent Number 5,656,725 teaches a method of screening for modulators of the interaction of a sequence comprising SEQ ID NO: 36 (i.e. SEQ ID NO: 2) and Bcl-XI, wherein Bcl-XI is labeled, and is a fusion protein which may be GST-Bcl-XI, and wherein said agent augments or inhibits dimerization between a sequence comprising SEQ ID NO: 36 and Bcl-XI. Said patent also teaches a method of screening for modulators of apoptosis comprising screening for modulators of the interaction of a GD domain as characterized in SEQ ID NO: 36, in view of the breadth attributed to the term "characterized".

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 46-55 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,221,615. Although the conflicting claims are not identical, they are not patentably distinct from each other because patented claim 1 closely parallels and embraces the instantly claimed invention.

The instant invention is drawn to a method of identifying a GD domain heterodimerization modulator comprising administering a test compound to a sample containing a polypeptide comprising SEQ ID NO: 36 and Bcl-Xl, or any protein containing a GD domain with Bcl-Xl, wherein the Bcl-Xl may be labeled, or wherein modulation comprises either augmentation or inhibition of heterodimerization.

The patented claim recites a method of identifying modulators of heterodimerization of any of SEQ ID NOS: 1-10, wherein SEQ ID NOS: 1-10 comprise an amino acid sequence found in the instantly claimed SEQ ID NO: 36, and a polypeptide of Bcl-Xl. Furthermore, the specification teaches that the Bcl-Xl polypeptide can be labeled as instantly claimed, and also teaches the method of identifying such inhibitors that comprise augmentation or inhibition of heterodimerization. Accordingly, the instant claims are considered to represent obvious variations of the patented method.

Claims 46-55 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,656,725. Although the conflicting claims are not identical, they are not patentably distinct from each other because patented claim 1 claims compounds that are used in the presently claimed methods. Because the specification discloses processes of screening for inhibitors of heterodimerization between the compounds of patented claim 1, and because methods of using compounds are considered obvious over the compounds themselves, the instantly claimed method of screening for inhibitors of heterodimerization is considered obvious over the patented claim.

***Allowable Subject Matter***

Claims 40-45 are allowed, because the amino acid sequence consisting of SEQ ID NO: 36 is considered to be free of the art.

***Conclusion***

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz, Ph.D. whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

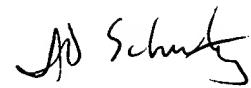
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JD Schultz, PhD



JAMES SCHULTZ  
PATENT EXAMINER